

REPORT TO CEN TC 55 ON TC 258 CLINICAL INVESTIGATIONS

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CD 14155, clinical investigation on humans, had been issued in 2007 and received a very large number of comments stretching to 36 pages. TC 194/WG4 prepared a revised draft which should have circulated as a second CD. However, the Secretariat DIN decided to issue a DIS, believing that the project might have been lost because it would not have met the timetabled deadline.

The vote and comments on the DIS have now been issued and the DIS has been rejected with yet another huge list of comments. In addition several Member Bodies have written separately complaining that the DIS should not have been issued but that a second CD was appropriate. Furthermore, several European Member Bodies and the CEN Consultant have written that the DIS does not address the new ER's of the revised MDD.

The opinion that the DIS is not suitable for Europe is of considerable concern. This concern needs to be addressed by CEN TC 258.